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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,423	10/22/2003	Joseph Oneal	APROG.0101	6169
22858 7590 08/06/2007 CARSTENS & CAHOON, LLP P O BOX 802334 DALLAS, TX 75380			EXAMINER KRISHNAN, GANAPATHY	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 08/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/691,423

Applicant(s)

ONEAL ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 5/21/2007 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

Remarks drawn to rejections under 35 USC 103(a)

Claims 1-17 are pending in the case.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 1-17 under 35 U.S.C. 103(a) as being unpatentable over Wright (Alternative Medicine, Townsend Letter for Doctors & Patients, July, 1999, page 96 and 98), Kumar et al (Indian Journal of Medical Research, 1982, 76 (suppl.), pages 46-53; see English abstract) newly cited, Carella et al (WO 97/29763) and Iwahi et al (J. Med. Microbiol., 1982, 15(3), 303-316) of record, is being maintained for reasons of record.

Applicants' have traversed the rejections advanced in the previous office action by arguing that while all the referenced prior art generally disclose the use of D-Mannose in the treatment of urinary tract infections, none of the prior art references teach the dosage and course of treatments disclosed in the claims of the present invention. Moreover, according to the applicants the dosage and course of treatments disclosed in the prior art is in line with the prior

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art methods and is distinguished from in the instant specification. Applicants' arguments are not found to be persuasive.

Wright teaches the use of D-Mannose for the treatment of urinary tract infections (page 96, left column, 4th paragraph; middle column, 3rd and 4th paragraphs; right column, first full paragraph). The dosage is one teaspoon, approximately 1-2.5 g, in the form of a powder dissolved in water, every three to four hours (page 96 right column, last paragraph and page 98, left column, first paragraph).

Carella et al teach the use of D-mannose in a composition for the promotion of a healthy environment in urogenital tracts and for treating urogenital disorders (page 2, lines 7-10 and 16-17; page 5, lines 15-16). The compositions can be administered as tablets, capsules (page 10, lines 7-10) and can contain 5 to about 75% per unit dose (page 6, lines 22-25). According to Carella additional ingredients and dosages can be readily ascertained using routine experimentation (page 14, lines 32-35). This means that the art recognizes that the dosages can be varied or frequency of administration adjusted till symptoms subside. Carella's teaching suggests adjustment of dosages and frequency of administration.

Kumar et al drawn to crataeva nurvala, teach that it is highly reputed for its therapeutic value in the treatment of urinary tract infections (see English abstract) and Iwahi et al teach that d-mannose is potent in inhibiting viral adhesion to the urinary tract (Abstract). Hence, there is a suggestion regarding the dosage and course of treatment in the prior art, especially Carella.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer d-mannose containing the herbal extracts as instantly claimed, to treat urinary tract infection since the use of mannose and the said herbal extracts like crataeva nurvala

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for the said treatment is seen to be taught in the prior art. One of ordinary skill in the art would be motivated to use d-mannose and pollen extract and extracts of crataeva nurvala and willow bark as the active agents since d-mannose is potent in preventing viral adhesions to the urinary tract as taught by Iwahi et al and the extracts of pollen, crataeva nurvala and willow bark have additional benefits as taught by Kumar.

It is well within the purview of one of ordinary skill in the art to include other herbal extracts known for treatment of urinary tract infections and also adjust the administration dosage and the amounts in the compositions as instantly claimed in order to get the maximum beneficial effects of the active agents.

Conclusion

Claims 1-17 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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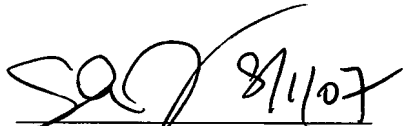
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


Shaojia Jiang
Supervisory Patent Examiner
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